Stop Guessing. Start Knowing.

OPAL1® PDD in Urology –
Flexible visualization with IMAGE1 S™
Bladder Cancer

Bladder cancer ranks as the ninth most common cancer worldwide with 430,000 new cases and more than 165,000 deaths annually. 75% of all bladder cancer cases occur in men. It has a high recurrence rate with an average of 60-80%, of which 40-60% recurs within 2 years. Bladder cancer has the highest lifetime treatment costs per patient of all cancers.

Fig. 1: Bladder cancer – facts and figures
Bladder cancer is a costly, potentially progressive disease for which patients have to undergo multiple cystoscopies due to the high risk of recurrence. There is an urgent need to improve both the diagnosis and the management of bladder cancer for the benefit of patients and healthcare systems alike.

Bladder cancer is classified into two types, non-muscle invasive bladder cancer (NMIBC) and muscle-invasive bladder cancer (MIBC), depending on the depth of invasion in the bladder wall. NMIBC remains in the inner layer of cells lining the bladder. These cancers are the most common (75%) of all BC cases and include the subtypes Ta, carcinoma in situ (CIS) and T1 lesions. MIBC is when the cancer has grown into deeper layers of the bladder wall. These cancers, including subtypes T2, T3 and T4, are more likely to spread and are harder to treat.

Photodynamic Diagnostics

Photodynamic Diagnostics (PDD) allows the visualization of early-stage malignant tumors that are invisible to the human eye and thus improves prognosis in patients. A timely detection of tumors in the early stages and full resection (if possible) greatly improve the prospects for recovery.

The principle of tumor detection is based on the altered metabolic activity of the tumor cells in heme-biosynthesis. The administration of Hexvix®/Cysview®, an intermediate product of heme-biosynthesis, leads to an increased accumulation of fluorescent protoporphyrin IX (PPIX) in the tumor cells. Thanks to the OPAL1® technology for PDD, the red color of these cells differentiates them from the surrounding tissue which has a blue color.

KARL STORZ, in conjunction with University Hospital Grosshadern in Munich, developed the first equipment for the PDD of bladder cancer as early as 1995. This technology is now used routinely in many clinics for bladder diagnostics. KARL STORZ thus set an important milestone in the early detection of bladder cancer.

Fig. 3: White light and PDD modes with the OPAL1® technology, based on IMAGE1 S™
Source: Priv.-Doz. Dr. med. Carsten Kempkensteffen, Charité, University Medical Center Berlin, Germany
Hexvix®/Cysview®

Hexvix®/Cysview® is a drug that is taken up by cancer cells in the bladder making them glow bright pink during blue light exposure, also known as Blue Light Cystoscopy (BLC™). The Hexvix®/Cysview® solution is administered into the bladder directly via a catheter. Hexvix®/Cysview® can be used in combination with both rigid and flexible PDD cystoscopes from KARL STORZ.

BLC™ with Hexvix®/Cysview® detects bladder cancer tumors that would have been missed with white light alone and results in better and earlier detection, more complete tumor removal, more accurate diagnosis and a reduced rate of recurrence and progression.

Key clinical evidence using rigid cystoscopes (in the OR) shows that BLC™ with Hexvix®/Cysview®:

- Detects additional tumors (Ta/T1) in 1 out of 4 patients
- Detects CIS (Carcinoma In Situ) in up to 1 out of 3 patients with CIS that would not be detected with White Light alone
- Results in 1 in 5 patients receiving more appropriate treatment
- Provides long-term benefits by significantly reducing rate and delaying time to recurrence
- Provides long-term benefits by significantly reducing risk and time to progression
- Safe and well-tolerated
- Very well accepted by patients

Cysview® is the tradename in the US and Canada, Hexvix® is the tradename in all other markets. Photocure is commercializing Hexvix®/Cysview® directly in the US and the Nordic region, and has strategic partnerships for the commercialization of Hexvix®/Cysview® in Europe, Canada, Australia and New Zealand. Please refer to https://www.photocure.com/Partnering-with-Photocure/Our-partners for further information on our commercial partners. Photocure, headquartered in Oslo, Norway, is a specialty pharmaceutical company focusing on urology. The company is listed on the Oslo Stock Exchange. Information about Photocure is available at www.photocure.com.

BLC™, BLFC™, Hexvix® and Cysview® are all trademarks protected by law and are registered trademarks of Photocure ASA.

Fig. 4: Hexvix®

* Indications and regulations vary by market; please refer to the approved indications by country.
Source for image and text: Photocure ASA
Expand your Perspective of IMAGE1 S™ with the OPAL1® Technology for PDD

KARL STORZ offers a complete solution for the treatment of bladder cancer – ranging from diagnostics to treatment and aftercare. The PDD imaging chain consists of several precisely matched components: The IMAGE1 S™ camera platform, particularly light-sensitive cameras, the high-performance D-LIGHT C light source, special endoscopes and light cables.

With PDD in FULL HD image quality, the IMAGE1 S™ camera platform acquires a further OPAL1® technology for fluorescence-assisted treatment thanks to the new HX-FI camera heads. As part of the modular platform, existing systems can easily be expanded to include PDD fluorescence imaging. This makes the systems futureproof and ready for new technologies.

Fig. 5: PDD technology, based on the IMAGE1 S™ camera platform
Source: Priv.-Doz. Dr. med. Carsten Kempkensteffen, Charité, University Medical Center Berlin, Germany
NEW

HX-FI (P) Camera Heads

Experience PDD in brilliant image quality

The HX-FI camera head series includes a standard and a pendulum camera head version. The connection to the X-LINK of the IMAGE1 S™ camera platform makes the HX-FI camera head series an attractive solution. In addition to flexible video endoscopes, rigid endoscopes can also be connected to this link module and displayed in white light and PDD.

The benefits of the previous HX camera head series have been retained in the HX-FI camera heads and have been further optimized. The HX-FI camera heads also impress with a compact design and a light weight. This makes them an optimal solution for interventions where a lightweight and ergonomic design is crucial. Furthermore, the OR team can begin work without extensive training, which promotes efficiency and patient safety.

Moreover, the HX-FI camera head series delivers excellent, crisp images in FULL HD quality in both white light and PDD.
Features of the HX-FI Camera Heads

Optical Properties

The optical properties of the HX-FI camera heads ensure that the monitor displays images produced by 4 mm telescopes as full circular images (Fig. 8). These camera heads are therefore ideal for small cavities. Through the digital zoom of IMAGE1 S™, a format-filling image can be generated on the monitor.
Flexibility in Visualization

The new multifunctional camera heads offer the user maximum flexibility in visualization. In addition to the OPAL® technology for PDD, the S-Technologies CHROMA, SPECTRA A* and SPECTRA B* can also be displayed in white light. These versatile visualization options can easily be accessed via the camera head buttons or live menu.

All visualization modes are designed to facilitate the differentiation of tissue structures through different displays or views and to thereby optimally support the user in the OR. A clear differentiation of tissue structures ultimately facilitates safer and more efficient procedures.

The OPAL® technology for PDD allows the visualization of tumors – particularly malignant tumors in the early stages – that are not visible to the naked eye. A reddish color clearly differentiates tumors from the surrounding tissue which is colored blue.

Fig. 9: Overview of S-Technologies
Source: Prof. Dr. Karl, Universitätssklinik München, Munich, Germany
* SPECTRA A: Pending 510(k) Clearance. Not available for sale in the U.S.
* SPECTRA B: Pending 510(k) Clearance. Not available for sale in the U.S.
**CHROMA: Technology for Contrast Enhancement**

CHROMA enhances the color contrast, without altering the user’s natural color perception. Each pixel's environment is analyzed with regard to the spatial color changes and is emphasized accordingly. Color changes and structures are thus represented more clearly and the borders between different tissue types are more apparent.

Fig. 10: Comparison with standard image – CHROMA in white light

**SPECTRA A*: Spectral Color Shift (filtration of reds) and Color Switch**

In SPECTRA A*, spectral filtering of the red hues takes place. This color change or switch is achieved by shifting color channels. The most delicate red structures, such as blood vessels and the mucosa, are clearly displayed in greenish-blue.

Fig. 11: Comparison with standard image – SPECTRA A* in white light

* SPECTRA A: Pending 510(k) Clearance. Not available for sale in the U.S.
* SPECTRA B: Pending 510(k) Clearance. Not available for sale in the U.S.
**SPECTRA B**: Spectral Color Shift (Intensification of Greens and Blues)

SPECTRA B reduces reds and intensifies the green-blue spectral component. The background appears greenish so that blood vessels and capillaries are highlighted. The user maintains a large amount of the natural color perception.

**Side-by-Side View**

Users can simply toggle between the standard image and the respective visualization mode. IMAGE1 S™ offers the possibility to simultaneously display and document both the standard image and the respective visualization mode (except PDD) on the same monitor.

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**Fig. 12**: Comparison with standard image – SPECTRA B* in white light

**Fig. 13**: Side-by-side viewing with IMAGE1 S™ – Source: Guido Kamphuis, M.D., Academisch Medisch Centrum, Amsterdam (The Netherlands)

* SPECTRA A: Pending 510(k) Clearance. Not available for sale in the U.S.
* SPECTRA B: Pending 510(k) Clearance. Not available for sale in the U.S.
Benefits at a Glance

Brilliant, razor-sharp FULL HD imaging in the white light and PDD modes

Diverse visualization options with OPAL1® technology combined in one system for PDD and S-Technologies

Possibility to adjust illumination in the PDD mode in three steps

New intelligent OPAL1® tile for uniform menu design for ease of use

Intuitive and rapid control via IMAGE1 S™, light source or footswitch

Impresses with lightweight and ergonomic design

Part of the modular IMAGE1 S™ camera platform – compatible with IMAGE1 S™ X-LINK

Optimally coordinated imaging chain for an excellent fluorescence effect in the PDD mode

Economical and futureproof. Existing systems can easily be expanded to include PDD imaging
The Optimal PDD Imaging Chain

“A chain is only as strong as its weakest link”. Consequently, the technology is based on several precisely harmonized components.

OPAL1® Technology for PDD *

- **Camera System**
  - IMAGE1 S™ System
  - IMAGE1 S CONNECT™ TC 200

- **Light Source**
  - D-LIGHT C/AF
    - 20136-01-1/20136-01-133

- **Camera Head**
  - IMAGE1 S™ HX FL/HX-P FL
    - TH 112/TH 113

- **Light Cables**
  - Fluid Light Cables
    - 495 FS/FO/FP/FR

- **Endoscopes**
  - HOPKINS® Telescopes
    - 27005 AIA/FIA/BIA/CIA

* Please verify that these components are approved for use in your country.
TC 200EN* **IMAGE1 S CONNECT™**, connect module, for use with up to 3 link modules, resolution 1920 x 1080 pixels, with integrated KARL STORZ-SCB and digital Image Processing Module, power supply 100-120 VAC/200-240 VAC, 50/60 Hz including:
- **Mains Cord**, length 300 cm
- **DVI-D Connecting Cable**, length 300 cm
- **SCB Connecting Cable**, length 100 cm
- **USB Flash Drive**, 32 GB
- **USB Silicone Keyboard**, with touchpad, US

TC 301 **IMAGE1 S™ X-LINK**, link module, for use with flexible video endoscopes and one-chip camera heads (up to FULL HD), power supply 100-120 VAC/200-240 VAC, 50/60 Hz, for use with IMAGE1 S CONNECT™ TC 200EN including:
- **Mains Cord**, length 300 cm
- **Link Cable**, length 20 cm

**Cold Light Fountain D-LIGHT C/AF SCB**, with integrated KARL STORZ-SCB, high-performance light unit for photodynamic diagnosis (PDD) ALA URO/ALA NEURO/Hypericine/Autofluorescence and for standard endoscopic diagnosis, with 300 Watt Xenon bulb, power supply 100-125/220-240 VAC, 50/60 Hz including:
- **Mains Cord**
- **SCB Connecting Cable**
- **One-Pedal Footswitch**, digital

* Also available in the following languages: DE, ES, FR, IT, PT, RU
Cold Light Fountain D-LIGHT C SCB, with integrated KARL STORZ-SCB, high-performance light unit for photodynamic diagnosis (PDD) ALA URO/ALA NEURO/ Hypericine and for standard endoscopic diagnosis, including a 300 Watt Xenon bulb and KARL STORZ light cable connection, power supply 100-25/220-240 VAC, 50/60 Hz including:

- Mains Cord
- SCB Connecting Cable
- One-Pedal Footswitch, digital, one-stage

**TH 112** IMAGE1 S™ HX FI One-Chip FULL HD Camera Head, S-Technologies (CHROMA, SPECTRA A and B) available, OPAL® technologies (PDD) in conjunction with light source D-LIGHT C or D-LIGHT C/AF, fixed focus, progressive scan, soakable, gas- and plasma-sterilizable, focal length f = 16 mm, 2 freely programmable camera head buttons, for use with IMAGE1 S™ (X-LINK)

**TH 113** IMAGE1 S™ HX-P FI One-Chip FULL HD Pendulum Camera Head, S-Technologies (CHROMA, SPECTRA A and B) available, OPAL® technologies (PDD) in conjunction with light source D-LIGHT C or D-LIGHT C/AF, with pendulum system and fixed focus, progressive scan, soakable, gas- and plasma-sterilizable, focal length f = 16 mm, 2 freely programmable camera head buttons, for use with IMAGE1 S™ (X-LINK)
27005 AIA  **HOPKINS® Straight Forward Telescope 0°**, enlarged view, diameter 4 mm, length 30 cm, **autoclavable**, for photodynamic diagnosis (PDD), fiber optic light transmission incorporated, special filter, color code: green

27005 FIA  **HOPKINS® Telescope 12°**, enlarged view, diameter 4 mm, length 30 cm, **autoclavable**, for photodynamic diagnosis (PDD), fiber optic light transmission incorporated, special filter, color code: black

27005 BIA  **HOPKINS® Forward-Oblique Telescope 30°**, enlarged view, diameter 4 mm, length 30 cm, **autoclavable**, for photodynamic diagnosis (PDD), fiber optic light transmission incorporated, special filter, color code: red

27005 CIA  **HOPKINS® Lateral Telescope 70°**, enlarged view, diameter 4 mm, length 30 cm, **autoclavable**, for photodynamic diagnosis (PDD), fiber optic light transmission incorporated, special filter, color code: yellow
It is recommended to check the suitability of the product for the intended procedure prior to use.